UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA *ex rel.* JOHN KING and TAMMY DRUMMOND, *et al.*, *Plaintiffs*,	§	
v.	§	CIVIL ACTION H-06-2662
SOLVAY S.A., *et al.*, *Defendants*.	§	

ORDER

Pending before the court is a motion for partial summary judgment on Relators John King and Tammy Drummond's (collectively, "Relators") off-label promotion theories of False Claims Act liability. Dkt. 476. The State of Texas has also filed a statement of interest related to this motion. Dkt. 592. Oral argument on this motion was heard on February 25 and 26, 2016. Having considered the motion, response, reply, oral arguments, Texas's statement of interest, and the applicable law, the court is the opinion that the motion for partial summary judgment (Dkt. 476) should be GRANTED.

I. BACKGROUND

The instant motion for partial summary judgment relates to Relators' allegations that defendant Solvay Pharmaceuticals Inc. ("SPI") promoted three drugs—Aceon, Luvox, and AndroGel[1] (the "Drugs at Issue")—off label and that the off-label promotion resulted in false claims

[1] All claims related to AndroGel have been dismissed under another theory. Dkts. 386, 585 (dismissing all AndroGel claims because they are barred by the state and federal False Claims Acts' public disclosure bars or the court otherwise lacks jurisdiction).

being submitted for prescriptions paid for by government health care programs.[2] Dkt. 476. Relators contend that this violates the federal False Claims Act ("FCA") and parallel statutes in numerous states. *See* Dkt. 154. SPI seeks summary judgment on these claims because (1) Relators do not have any admissible evidence of false claims; and (2) Relators cannot establish a causal nexus between any alleged fraudulent conduct and any false claims. Dkt. 477. Relators contend that they have ample proof that SPI's marketing of Luvox and Aceon[3] caused ineligible false claims to be presented to government health care programs. Dkt. 596. SPI argues that (1) proof of false claims is a required element of False Claims Act liability and that Relators must therefore identify a universe of false claims; (2) Relators' summary chart including examples of claims relating to 28 physicians in Texas and New York is inadmissible; and (3) even if it were admissible, the data provided is full of errors and cannot create an issue of material fact. Dkt. 610. Relators argue that they do not need to identify a universe of false claims, that the evidence they offer is admissible, and that the evidence creates a genuine issue of material fact for trial. Dkt. 616.

II. LEGAL STANDARD

A court shall grant summary judgment when a "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "[A] fact is genuinely in dispute only if a reasonable jury could return a verdict for the non-moving party." *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material

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[2] SPI is now know as AbbVie Products, LLC. Dkt. 476.

[3] While the court has, at times, addressed Relators' arguments related to their AndroGel claims in an abundance of caution even though all AndroGel-related claims have already been dismissed, Relators did not brief their AndroGel claims in their opposition to the instant motion.

fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). If the party meets its burden, the burden shifts to the non-moving party to set forth specific facts showing a genuine issue for trial. Fed. R. Civ. P. 56(e). The court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant. *Envtl. Conservation Org. v. City of Dall., Tex.*, 529 F.3d 519, 524 (5th Cir. 2008).

III. ANALYSIS

The court starts and ends its inquiry with SPI's objections that the evidence upon which Relators rely in their opposition is not admissible. Under Federal Rule of Civil Procedure 56(c), a party asserting that

> a fact is genuinely disputed must support that assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials.

Fed. R. Civ. P. 56(c)(1). Then, a "party may object that the material cited to support . . . a fact cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2).

SPI's objections to Relators' evidence are numerous. SPI objects, primarily, to Relators' reliance on underlying Medicaid pharmacy claims data from Texas and New York (the "Texas Claims Data" and the "New York Claims Data"). The Texas Claims Data and New York Claims Data relate to claims from pharmacies for reimbursement from the Texas and New York Medicaid programs for prescriptions of the Drugs at Issue. SPI contends that the Texas Claims Data and New York Claims Data lack foundation and have not been authenticated. Dkt. 610; *see also* Dkt. 400 at 13. The Texas Claims Data and New York Claims Data are not part of the summary judgment record, but Relators relied on the Texas and New York Claims Data to create summary charts that

are part of the record.[4] SPI objects to the summary charts because they are based on the Texas and New York Claims Data, which is inadmissible, and because Relators did not disclose who created the summary charts or explain how they were created. *Id.* SPI also objects to Realtors' reliance on call notes from SPI sales representatives, which are included in the summary charts, because the call notes contain hearsay and lack foundation. *Id.*

After the initial objection to the authenticity of the underlying data contained within SPI's motion for summary judgment on Relators' Anti-Kickback Statute claims (*see* Dkt. 400)—a different motion for summary judgment that was filed earlier than the instant motion—Relators provided an affidavit and declarations from three individuals in an attempt to properly authenticate the Texas data.[5] *See* Dkt. 415 (Relators' response to the motion for summary judgment on the Anti-Kickback statute). They have not, to this date, provided any declarations to support the New York data. The court will address the admissibility of the New York Claims Data first, then it will discuss the admissibility of the Texas Claims Data, the summary charts, and the call notes.

A. Admissibility of New York Claims Data

Relators claim that they have been unable to obtain a declaration to support the New York data due to the high turnover at the New York state agency that provided the data. They argue, however, that the New York Claims Data is self-authenticating because it was produced pursuant

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[4] Relators note that SPI has the Texas and New York Claims Data in its possession but that, because it can be difficult to read, Relators did not attach it to the response. Dkt. 596 at 30 n.133. Instead, they offer to provide it for the court's inspection upon request. *Id.*

[5] The court has already ruled on the motion for summary judgment on the Anti-Kickback Statute claims. *See* Dkt. 621. However, the court did not address the evidentiary issues because Relators did not have sufficient evidence to raise an issue of material fact even if the evidence were admissible. *See id.*

to a subpoena. They additionally argue that the data is what it purports to be under Federal Rule of Evidence 901. Relators indicated during the hearing that if the court determines the data is not self-authenticating and does not accept it under Rule 901, they would likely need to serve another subpoena requesting the New York Claims Data again to obtain a declaration authenticating the data.

1. Self–Authenticating

Relators contend that the New York Claims Data is self-authenticating because it was produced pursuant to a subpoena. They rely primarily on *United States v. Hubbell*, 167 F.3d 552, 567–68 (D.C. Cir. 1999), *aff'd*, 530 U.S. 27, 120 S. Ct. 2037 (2000). *See* Dkt. 616 at 9 n.15. *Hubbell* is a criminal case in which the defendants moved to dismiss an indictment charge of tax evasion because, among other reasons, the prosecution would "depend on evidence produced under compulsion and used in violation of the Fifth Amendment." 167 F.3d at 554. The defendant, after receiving an order signed by a judge that directed him to respond to a subpoena and granted him immunity to the extent allowed by law, turned over 13,120 pages of documents and records to Independent Counsel Kenneth Starr. *Id.* at 565. When being questioned by the Independent Counsel in front of the Grand Jury, the defendant answered that he had provided the documents. *Id.* Evidence found in these documents resulted in an indictment that charged the defendant and others with, among other things, conspiracy to defraud the United States Department of Treasury, the Internal Revenue Service, and others. *Id.* The district court found that the defendant had "communicated the authenticity and his possession of the documents" and "implicitly testified as to the very existence of the documents," but that since Independent Counsel had "no source of knowledge independent of [the] immunized act of production," Independent Counsel violated the

defendant's Fifth Amendment rights when he used the documents. *Id.* at 567. On appeal, the D.C. Circuit found:

> [T]he act of production communicates at least four different statements. It testifies to the fact that: i) documents responsive to a given subpoena exist; ii) they are in the possession or control of the subpoenaed party; iii) the documents provided in response to the subpoena are authentic; and iv) the responding party believes that the documents produced are those described in the subpoena.

Id. at 567–68 (footnote omitted). The court noted that the authenticity prong "strongly implies that authenticity refers to something other than the party's belief that surrendered documents match those described in the subpoena." *Id.* at 567 n.20. The court discussed authenticity "in terms of admissibility under Rule 901" and recognized that "the act of production *could* relieve the government of the need to authenticate evidence." *Id*. (emphasis added).

Here, while certainly Relators' assertion that the State of New York produced the New York Claims Data pursuant to a subpoeana lends credence to the idea that the New York Claims Data must be what was requested in the subpoena,[6] *Hubbell* does not instruct that documents produced pursuant to a subpoena are always self-authenticating. As noted by SPI, this case is different than *Hubbell* and the cases cited by the *Hubbell* court because those cases involved documents produced pursuant to a subpoena that were going to be used *against* the producing party. Here, Relators sued, in part, on behalf of the state of New York. Thus, to the extent Relators would rely on the New York claims data to prove that SPI promoted the Drugs at Issue to New York physicians who prescribed the drugs to New York patients who then obtained prescriptions that were paid for, in part, by New York Medicaid, Relators would be using the subpoenaed documents to *benefit* New York. Thus, the

[6] It does not appear that the New York subpoena is in evidence.

situation is actually the opposite of the situation in *Hubbell*. The court finds that Relators have not shown that the New York claims data is self-authenticating simply because it was produced pursuant to a subpoena.

2. Rule 901

During the hearing, Relators' counsel urged the court to accept the New York Claims Data for what it purports to be under Federal Rule of Evidence 901(b)(4). Under Rule 901(b)(4), evidence satisfies the authentication requirement if the "appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances" support a finding that the evidence is what the proponent claims it is. Fed. R. Evid. 901(b)(4). The New York Claims Data is not in evidence, but it is clear from the briefing and the arguments at the hearing that the data is unwieldy and that the data cannot be interpreted without testimony regarding what was included in the dataset and how it was compiled. There is, however, no affidavit from the person who compiled the dataset in the record. Instead, Relators offer a declaration from their lead counsel stating only the summary charts accurately present the underlying material from the New York Claims Data and that Relators organized the New York Claims Data using a consultant, Greylock McKinnon, who used the same coding that was applied by SPI's expert. *See* Dkt. 596, Ex. D4. While this is somewhat helpful in understanding how the summary charts were compiled, it does not assure the court that the underlying database is what it purports to be.

Relators have not shown that the New York Claims Data can be presented in a form that will be admissible at trial. Accordingly, SPI's objection to the New York Claims Data is SUSTAINED.

B. Admissibility of Texas Claims Data

SPI also objects to the authenticity of the Texas Claims Data. Dkt. 610. Relators provide

an affidavit and two declarations to support the authenticity, but SPI objects to the affidavit and declarations because the witnesses were not disclosed. Relators contend that they either did not have to disclose the witnesses or that any error is harmless, and, like with the New York Claims Data, Relators urge the court to accept the Texas Claims Data under Federal Rule of Evidence 901. The court will first addresses the three witnesses and then discuss Rule 901.

1. Surprise Witnesses

SPI objects to Relators' reliance on the declarations of the three witnesses that Relators supplied in response to the motion for summary judgment on the Anti-Kickback statute to authenticate the Texas Claims Data. SPI contends that Relators cannot rely on these witnesses because they were never disclosed, and SPI thus had no opportunity to depose them during discovery, which concluded long ago. Dkt. 446. SPI points out that it specifically requested the names of the person or persons who would authenticate the claims data in Interrogatory No. 10, and Relators objected to the interrogatory, stating that they "need not identify the person or persons who could testify at trial to support the authenticity of the Claims Data at this time," citing Federal Rule of Civil Procedure 26(a)(3)(B). Dkt. 399, Ex. 5 at 117 (interrogatory responses dated Dec. 1, 2014). SPI further argues that even if the court were to allow the testimony of these three witnesses, the declarations and affidavit are insufficient to authenticate the data. Dkt. 446.

Relators explain that the Office of the Attorney General for the State of Texas ("OAG") obtained the Texas Claims Data pursuant to a State Action Request in 2006 and produced the data to Relators in raw form. Dkt. 415 (Relators' response to SPI's motion for summary judgment on the Anti-Kickback Statute). They provide an affidavit from the Litigation Section Chief of the Texas Health and Human Services Commission ("HHSC")—the state agency responsible for administering

the Medicaid program in Texas. Dkt. 419, Ex. 17. The Texas Medicaid Health Partnership ("TMHP") is a contractor for Texas HHSC. *Id.* According to the Litigation Section Chief of HHSC, Kevin Raymond, TMHP created and provided data extracts in response to a request to "run an ad hoc query involving several drugs identified according to NDC codes specified by the OAG." *Id.* The TMHP provided the data via CD-ROMs to an unspecified OAG representative on January 17, 2006. *Id.*

Relators next provide a declaration from Anthony Maro of EvriChart, Inc. Dkt. 419, Ex. 18. Maro states that he received "raw Texas Medicaid claims data for Luvox, Aceon, and AndroGel" in 2006 and converted it into Excel spreadsheets for each of those drugs. *Id.* These spreadsheets contained several columns, including a column for primary and secondary diagnosis codes. *Id.*

The third declaration is from Karen Karban, who was a contract medical coder with Healthcare Contract Resources in 2006. Dkt. 419, Ex. 19. Karban asserts that she received the spreadsheets from Maro and used them to create separate spreadsheets for each of the drugs based on on-label and off-label diagnosis codes and descriptions. *Id.*

Relators contend that they produced a flash drive to SPI containing the patient-specific Texas Claims Data described in Karban's Declaration. Dkt. 415 at 25 (citing a letter to SPI's counsel dated May 14, 2014 (Ex. 37)). Relators assert that they also produced three spreadsheets with prescription data for top Texas Medicaid prescribers for Aceon, AndroGel, and Luvox; prescription data for top New York Medicaid AndroGel prescribers; raw New York Claims Data; Florida Medicaid utilization data; Virginia utilization data; and a list of top Virginia Medicaid prescribers for Luvox, Aceon, and AndroGel. *Id.* at 25–26.

SPI asserts that "a cursory review of the affidavit and declarations and Karban's spreadsheets reveals that they are not simply data extracted from records of the Texas Medicaid pharmacy claims" as they "include far more information than a record of pharmacy claims would." Dkt. 446 at 8. SPI argues that the data must have been augmented in an undisclosed way and that perhaps Relators do not even understand the origins of the data. *Id.* at 9. SPI points out that Karban's spreadsheet contains columns labeled "Dtl_Diagn" for diagnosis codes and "Dtl_Diag_Desc" for diagnosis descriptions, yet there is no diagnosis data on the Medicaid/CHIP Vendor Drug Program Pharmacy Claims Billing Request Form, which is presumably what the state would have used to compile the pharmacy claims data. *Id.*; *see* Dkt. 446, Ex. 3 (example of Karban spreadsheet). SPI urges the court to rule that neither the spreadsheets nor the surprise witness declarations are competent summary judgment evidence. Dkt. 446 at 9.

Under Federal Rule of Civil Procedure 26(a)(1),a party in a case like this case must disclose "the name and, if known, the address and telephone number of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment." Fed. R. Civ. P. 26(a)(1). Under Rule 26(e), a party must supplement or correct its disclosures and responses to discovery "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Fed. R. Civ. P. 26(e). Under Rule 37(c)(1), if a party fails to disclose or supplement as required by Rule 26, "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).

Relators did not disclose Raymond, Maro, or Karban as individuals who were likely to have discoverable information under Rule 26(a)(1)(A)(i), and they did not provide their names in response to SPI's Interrogatory No. 10.[7] They objected to the interrogatory, citing Federal Rule of Civil Procedure 26(a)(3)(B). *See* Dkt. 399, Ex. 5 at 117 (interrogatory responses). Rule 26(a)(3)(B) deals with the timing of *pretrial* disclosures. Under Rule 26(a)(3)(A), parties must, *in addition* to the disclosures required under Rule 26(a)(1) and (2), provide information about the evidence they will present at trial other than solely for impeachment, including providing information about witnesses the party may call if the need arises. Fed. R. Civ. P. 26(a)(3)(A). Rule 26(a)(3)(B) states that these disclosures must be made 30 days before trial, unless the court orders otherwise. *Id.* This requirement for pretrial disclosure of witnesses clearly states it is in "addition to the disclosures required by Rule 26(a)(1) and (2)," not in lieu of the requirement. Relators' abilities to create an issue of material fact and, if they survive summary judgment, convince a jury that SPI used off-label marketing that resulted in false claims hinge on the Texas Claims Data contained in the spreadsheets that were created by these witnesses. These people have discoverable information and should have been disclosed long ago.[8]

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[7] Interrogatory 10 states: "For all **Claims Data** referenced in your responses to SPI's Interrogatories No. 2 and 9, **Identify** the person or person who could testify at trial to support the authenticity of the **Claims Data**." Dkt. 399, Ex. 5 at 117. Relators' response states: "Relators object to this interrogatory because Relators need not identify the person or persons who could testify at trial to support the authenticity of the Claims Data at this time. See FED. RULES OF CIV. P. 26(a)(3)(B)." *Id.*

[8] During the hearing, Relators' counsel noted that Maro organized the data in 2006. They liken his role to that of eyeglasses that would help the Relators and the court see the data. They claim that they did not disclose him earlier because they felt it was just a "technical issue" and they did not believe his testimony would be needed. With regard to Karban, Relators assert she is a coding expert, does "not have a lot of consequence," and they "probably were not required to disclose her." It should have become clear at least by the time that SPI served Interrogatory 10 that

Relators have not provided substantial justification for not disclosing these witnesses and they have not shown that the failure was harmless. Under Rule 37, if a "party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless."[9] Fed. R. Civ. P. 37(c). In their surreply and at the hearing, Relators indicated that they believed the failure to disclose was harmless because a trial date has not yet been set and it would be easy to reopen discovery so that SPI could depose these witnesses prior to trial. The court disagrees that the failure to disclose is harmless. This case is over ten years old. As of February 25, 2016, there are 635 docket entries in this case. Discovery ended and the dispositive motion deadline expired long ago. There were numerous motions for summary judgment filed as well as ten motions to exclude experts. Thousands of pages were filed in support of or in opposition to these motions. There is no trial date at this point only because the court has had to expend significant resources trying to cull through all of this paperwork. One of the arguments advanced by SPI in support of at least two of its motions for summary judgment and discussed in relation to some of the experts is that Relators had not authenticated the Texas Claims Data or provided the names of any witnesses who could do so during discovery. Allowing Relators to disclose witnesses who can authenticate the data that forms the backbone of their case after the

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how the data was manipulated would become an issue in the case and that the people who did so were individuals with discoverable information.

[9] The court may impose alternative sanctions in addition to or instead of not allowing the evidence "upon motion and after giving an opportunity to be heard." *See* Fed. R. Evid. 37(c)(1). However, Relators did not request an alternative sanction.

close of discovery and well after all dispositive motions were due would cause significant prejudice to SPI and would be a waste of judicial resources.

This is particularly true because even if the court were to consider the declarations and affidavit at this point, they are insufficient to authenticate the Texas Claims Data. While Raymond's affidavit indicates that he reviewed the records and a "query was run," he does not say that he has personal knowledge of these searches, specify that the queries related to the Drugs at Issue, or indicate to whom the data was delivered. Dkt. 419-4 ¶¶ 4–5. He notes that the data was kept by TMHP "in the regular course of business," but he works for HHSC, not TMHP, and there is no affidavit from the custodian of records for TMHP.[10] *See id.* ¶ 6. Maro's declaration does not state who gave him the raw Texas Medicaid claims data or where he found the diagnosis data. *See* Dkt. 419-5. Karban's declaration states that she used spreadsheets obtained from Maro to make new spreadsheets for each drug that included whether the diagnosis codes were on-label. *See* Dkt. 419-6. The court gathers, based on counsel's representations at the hearing, that Maro's spreadsheets had numerical codes for the diagnoses and that Karban converted those numerical codes into verbal names. The court also learned during the hearing that Maro and Karban attempted to match up multiple data sets in 2006, which is how the diagnoses codes were added to the pharmacy data. This was not in the declarations or affidavit. Presumably, SPI would have learned all of this during

[10] This is entirely different than in a case Relators rely on, *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 161 (D.D.C. 2008). In *Pogue*, the relator relied on data from the Centers for Medicare & Medicaid Services ("CMS"). *Id.* An official at CMS assembled claims data in response to the relator's subpoena onto a CD and provided the data to the relator. *Id.* The relators produced the declaration of the official who assembled and provided the data. *Id.* Here, the declarant is *not* the official who compiled the data and does not even work for the same agency as the official who compiled the data.

discovery if Relators had disclosed these witnesses.[11] SPI would have then been able to test the reliability of the witnesses' methods with questions during depositions.

Relators assured the court during the hearing that they would be able to adequately authenticate the data by trial, but this assurance rings hollow. It is simply not appropriate to allow a party to wait until trial to disclose witnesses that should have been disclosed well before summary judgment motions were due so that the opposing party would have a chance to depose the witnesses and determine whether their methods in compiling the data were reliable and whether the data is what it purports to be.[12] The court's ability to rely on this data is key to whether Relators can show there is an issue of material fact supporting their claims, and its reliability needed to be tested before dispositive motions were filed. Because the witnesses were not disclosed and Relators have not

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[11] Magistrate Judge Nancy Johnson held a discovery conference relating to some allegedly inadequate responses to SPI's interrogatories about the claims data. *See* Dkt. 325 (transcript). Relators asserted that they had "not held back information such as correspondence about claims data" and that if SPI did not "know what to do with the New York data it is not because they're missing . . . extensive ledgers that explain it all." *Id.* at 22. At that hearing, Judge Johnson ruled that Relators' responses were adequate, given their representations at the hearing, but warned that if Relators had other information or if "at some point in discovery or in motion practice, if something is not there, [then] Judge Miller may hold that against [Relators]." *Id.* at 30. Judge Johnson agreed with SPI that at some point Relators may not be able to "connect the dots," but that at that point they did not have to outline all of their claims in the response to the interrogatories that were the subject of the hearing. *Id.* at 30. While this hearing was not about Interrogatory 10, the fact that Relators insisted that they had provided all the information about claims data at that point and were warned that if they failed to do so it may be an issue later in the case proved prescient.

[12] The court notes that it assured counsel during the hearing that it did not believe that she had simply made up the data. According to the arguments at the hearing and information deduced throughout this case's history, the court agrees with counsel that the data is far too voluminous for counsel to have made it up. However, the court must abide by the Federal Rules of Evidence, which the United State Supreme Court has instructed govern procedure in the United States District Courts. *See* Fed. R Evid., Orders of the Supreme Court of the United States Adopting and Amending the Rules (Nov. 20, 1972). Counsel "must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901.

shown that the failure to disclose them was harmless or substantially justified, the court finds that, under Rule 37, Relators cannot rely on witnesses Raymond, Maro, or Karban.

2. Rule 901

During the hearing, Relators' counsel urged the court to accept the Texas Claims Data for what it purports to be under Federal Rule of Evidence 901(b)(4) and asserted that they are not required under this rule to show who created the document. Evidence satisfies the authentication requirement under Rule 901(b)(4) if the "appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances" support a finding that the evidence is what the proponent claims it is. Fed. R. Evid. 901(b)(4). The Advisory Committee Notes for this rule indicate that, for instance, "a document or telephone conversation may be shown to have emanated from a particular person by virtue of its disclosing knowledge of facts known peculiarly to him." Fed. R. Evid. 901, Advisory Comm. Notes. Similarly, a letter that indicates it is in reply to an authenticated letter may be authenticated by this content, and language patterns may indicate authenticity. *Id.*

Here, Relators state that the distinctive characteristics of the Texas Claims Data indicate that it is what it purports to be. The problem with attempting to place the Texas Claims Data in this category is that even if it is clear that some or most of the data came from Texas Medicaid, there is no proof that nothing was *added* to that data when the spreadsheets upon which Relators rely were created. Moreover, the fact that diagnosis codes would not be available in *pharmacy* claims data but yet are listed on the spreadsheets makes the assertion that the court can rely on the data as authentic simply because it must be Texas pharmacy claims data unsustainable. Clearly Karban or Maro added something from another dataset to the Texas Claims Data.

Relators also asserted during the hearing that it does not matter that they did not disclose who created the data spreadsheets because Rule 901 does not requiring such a showing, citing *Burden v. Bar Louie Anaheim*. In *Burden*, a slip-and-fall case that had reached the summary judgment stage, a federal district court in the Central District of California discussed the plaintiff's objection to the defendant's summary judgment evidence. *Burden v. Bar Louie Anaheim, Inc.*, No. SACV 15-0638 AG (E), 2016 WL 551993, at *1–2 (C.D. Cal. Feb. 10, 2016). One of the objections related to a declaration by Kerry Paredes, who appears from his title to be an in-house lawyer for the defendant's parent company, because he was not identified in discovery responses or in the defendant's initial disclosures. *Id.* While the order does not provide a complete description, it appears that Parades's declaration was merely describing the attached exhibits. *Id.* The exhibits had been disclosed during discovery, and the plaintiff admitted that the defendant named Paredes as an individual who helped prepare discovery responses. *Id.* The plaintiff objected to the authentication of the attached documents because there were no facts about their creation or formation, but the court found that the declaration and content of the documents were sufficient to show that the documents were what they claimed to be under Rule 901(b)(1). *Id.* The court also found that Paredes was qualified to certify the documents' authenticity. *Id.*

Here, Relators' counsel, like the defendant's counsel in *Burden*, provides a declaration with the exhibits to the Relators' response. Dkt. 596, Ex. D4. She asserts that Appendix A contains summary charts that summarize acts of off-label promotion and that these charts "accurately and correctly present[] the underlying material from the promotional evidence and claims data." *Id.* However, unlike the lawyer in *Burden* who the court determined was qualified to certify the document's authenticity, the court finds that Relators' counsel is not qualified to authenticate the

Texas Claims Data. She does not say how the charts were created or provide any information about why the underlying claims data is what it purports to be. Thus, neither *Burden* nor the declaration alleviate the court's concern about the Texas Claims Data and they certainly do not convince the court that the data is what it purports to be under Rule 901.

Relators have not shown that the Texas Claims Data can be presented in a form that will be admissible at trial. Accordingly, SPI's objection to the Texas Claims Data is SUSTAINED.

C. Call Notes as Proof of Off-Label Promotion

SPI also objects to the call notes that Relators rely on to show that SPI promoted the Drugs at Issue off label. Dkt. 610. The "call notes" are notes that SPI's sales representatives made to document their sales calls to physicians' offices. The parties agreed during the hearing that there is no issue with whether the call notes are authenticated, as they were supplied by SPI. SPI, however, asserts a hearsay objection to the call notes to the extent they contain statements by physicians. SPI also argues that Relators have not properly laid the foundation for these call notes, as they provide no evidence regarding the purpose of call notes or what types of information the sales representatives were required to document. Dkt. 610 at 15. Relators contend that most statements by physicians contained within the call notes are in the form of a question and thus not "statements" and not hearsay. Dkt. 616. They also assert that this type of evidence was used without question in *United States ex rel. Franklin v. Parke-Davis*. Finally, Relators contend that they do not have to produce evidence that is cross-examination proof.

1. Hearsay

First, the court finds that the statements made by physicians in the call notes are hearsay. Under Federal Rule of Evidence 801, hearsay is a statement that a declarant does not make while

testifying at a hearing or in a current trial and that "a party offers in evidence to prove the truth of the matter asserted in the statement." Fed. R. Evid. 801(c). While certainly some of the statements made by physicians in the call notes take the form of questions, these questions are being used for the truth of the matter asserted—that the physician asked certain off-label questions about the Drugs at Issue.

The cases Relators cite in support of their hearsay position do not support their argument that the court should allow the physician statements into evidence in this case. In *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 CIV 1452(JGK), 1999 WL 509471 (S.D.N.Y. July 19, 1999), Zeneca, Inc. sued Eli Lilly and Co. for unfair competition and deceptive trade practices, and Barr Laboratories intervened. 1999 WL 509471, at *1. Eli Lilly objected to the admissibility of call notes that were written by its sales representatives about their dealings with physicians. *Id.* at *2. The court noted that it may consider hearsay when determining whether to issue a *preliminary injunction* and that, even if it could not, the notes satisfied the business records exception to the hearsay rule. *Id.* (citing Fed. R. Evid. 803(6)). Here, while it is possible that the call notes satisfy the business records exception, thus curing the first level of hearsay, the business records exception does not apply to the physicians' statements within the call notes, which are hearsay within hearsay. *See* Fed. R. Evid. 805 ("Hearsay within hearsay is not excluded by the rule against hearsay if each part of the combined statements conforms with an exception to the rule."); *United States v. Gwathney*, 465 F.3d 1133, 1141 (10th Cir. 2006) (noting that "business records are potentially fraught with double hearsay" and that "[a]ny information provided by another person, if an outsider to the business preparing the record, must itself fall within a hearsay exception to be admissible").

In *United States v. Lewis*, 902 F.2d 1176, 1179 (5th Cir. 1990), the Fifth Circuit considered whether to allow testimony of a police officer about what an unidentified caller said after the officer called a number sent to the defendant's pager. The court determined that the testimony was not hearsay because the questions asked by the unknown caller were not "statements" within the definition of hearsay. 902 F.2d at 1179. The court determined that the questions asked by the person the officer spoke to after calling the number on the pager were not "assertions" under the hearsay rule, because the questions were not intended to assert anything. *Id.* Here, of course, Relators are using the mere existence of the questions to assert something—that the physicians asked questions relating to off-label uses of the Drugs at Issue. Relators allege that these questions were prompted by the sales representatives' promotion of off-label uses. Therefore, the court finds that any physician questions documented within the call notes are hearsay.

Regardless, Relators urge the court to follow the example of the court in *Parke-Davis*, which Relators contend relied on evidence similar to the call notes without reservation. In *Parke-Davis*, the relator produced circumstantial evidence of the rates of off-label prescriptions before and after physicians attended conferences hosted by Parke-Davis and direct evidence of market-research reports recording the physicians' states of mind after the marketing meetings. *United States ex rel. Franklin v. Parke-Davis*, No. Civ. A. 96-11651PBS, 2003 WL 22048255, at *5 (D. Mass. Aug. 22, 2003). The relator also provided analysis linking patients' treatment histories to prescriptions of the drug at issue in that case, and they contended that many of the reimbursement claims must have been for off-label, non-compendium indications due to the patients' treatment histories. *Id.* at *4. While the defendant contested the reliability of comparing the pharmacy claim forms with diagnosis data from the patient medical-services forms, the court found that the relator's expert evidence was

sufficient to survive summary judgment. *Id.* The court deferred ruling on whether the sample the relator had of the prescription activities of ten physicians could be reliably extrapolated to measure nationwide damages until a later date. *Id.* at *5. There are, however, no further opinions relating to this case, so the court likely never reached that issue. While there are many similarities between this case and the *Parke-Davis* case, the issues with the evidence in *Parke-Davis* are *not* sufficiently similar to the evidentiary issues presented here to make the *Parke-Davis* court's decision to allow the evidence at the summary judgment stage persuasive. SPI's objection to the physicians' statements and questions in the call notes as hearsay is SUSTAINED. The court notes that the parties agreed during the hearing that if the court found that the physician statements/questions were hearsay, the parties could redact that portion of the call notes for trial.

2. Sufficiency of the Evidence

The court agrees that Relators are not required to produce evidence that is cross-examination proof. However, they are required to produce evidence that can be presented in a form that would be admissible at trial and that is sufficient to raise an issue of material fact. Even if the court presumes that Relators will lay the foundation for the call notes at trial, Relators failed to provide call notes sufficient to raise an issue of material fact that unlawful marketing allegedly documented in these call notes caused the physicians to write the prescriptions for the Drugs at Issue that were later the subject of claims for payment from the Texas Medicaid and United States Medicaid programs. The evidence presented via briefing and at the hearing would require a jury to draw inference upon inference to find a claim was submitted after a sales representative delivered an off-label message to a particular physician, and, *if* all of these inferences were reasonable, which they

are not, then Relators could only show a handful of visits to Texas physicians resulted in a false claim. *See* Dkt. 610.

While there are numerous examples in the briefing, the court will rely on the examples that were highlighted during the hearing. During the relevant time period, Aceon was approved by the federal Food and Drug Adminstration ("FDA") to treat "essential hypertension." *See* Dkt. 154 at 53. Relators contend that SPI promoted Aceon off-label by delivering messages about "arterial wall compliance," the "diabetic kidney," and the PROGRESS study, all of which related to using Aceon for conditions not approved by the FDA. *Id.* at 54–55. Luvox was approved for the treatment of Obsessive Compulsive Disorder ("OCD"). *Id.* at 28. Relators contend SPI promoted Luvox off-label to treat conditions such as depression,[13] conditions on the Obsessive-Compulsive Spectrum ("O-C Spectrum"), and anxiety-related disorders. *Id.* at 32–33.

In the first example discussed extensively at the hearing, Relators pointed to a prescription that was written and filled on January 19, 2000, for Luvox for infantile autism. The call notes indicate that a sales representative introduced himself to the prescribing physician in December 1999 and that the physician informed the sales representative that he liked Luvox "for OCD and depression." Dkt. 596, App. A2.8. The sales representative noted that he would be visiting this physician every three weeks. *Id.* However, the next call note is not until March 30, 2000, which is *after* the date of the Luvox prescription for infantile autism. In this call note, the sales representative noted that he discussed the Stein article with the physician and that *the physician* told the sales

[13] While Relators contend that SPI promoted Luvox "off-label" for depression, physicians could lawfully prescribe Luvox off-label for depression because it is a use that is listed in DrugDex. *See* Dkt. 595 (dismissing Relators' fraud on DrugDex claims). Thus, any claim for reimbursement of a prescription of Luvox that was written because the patient was diagnosed with depression was not a "false claim."

representative about the Hollander article. *Id.* Relators' counsel noted during the hearing that both the Stein and Hollander articles relate to using Luvox to treat disorders in the O-C Spectrum, and that autism is sometimes included in this spectrum. *Id.* The call note goes on to state that the physician was "[v]ery happy with luvix [sic.] in [Post Traumatic Stress Disorder ("PTSD")] and panic" because the physician had "had [his or her] own episode with PTSD and [was] doing well with 75 mg/d." *Id.* Relators argued that there must have been calls between the initial call date and the date of the second entry and that the sales representative must have pitched Luvox for OCD and PTSD. One could infer that the sales representative did visit the physician between the two notes and did not document it because he stated that he would be calling on the physician frequently. However, there is *no* mention in any of the notes about autism. The call notes clearly indicate the physician was doing his or her own research. It would be unreasonable for a jury to conclude, based on this evidence, that the physician chose to prescribe Luvox to this patient for infantile autism because the sales representative must have pitched it for that use at some point.

This same physician prescribed Luvox for agoraphobia with panic on April 15, 2000, which is about two weeks after the sales representative reported that the physician discussed the Stein and Hollander articles with the sales representative. *Id.* SPI pointed out during the hearing that this same patient had been diagnosed with depression previously, and any claims for Luvox prescriptions for depression are reimbursable. Relators contended that the patient was diagnosed with depression by a different physician and that one of the Relators can testify that the Stein article is about social phobia, which is presumably related to agoraphobia with panic. Moreover, Relators assert that they will present evidence that SPI sales representatives were required to put this off-label information in front of the physicians. The problem is, they did not provide any of this evidence in the summary

judgment record, and this is the stage where they must provide enough evidence—as opposed to arguments and speculation—to demonstrate that there is an issue of material fact for trial.

The next example highlighted at the hearing is from the same physician, who prescribed Luvox, multiple times, to a patient with Attention Deficit Hyperactive Disorder ("ADHD") and autism. *Id.* There is no connection between the pitch, which appears to relate solely to what the physician said (hearsay) with the exception of a "discussion" of the Stein article, and ADHD or autism. It would be unreasonable for a jury to conclude that the possible provision of the Stein article caused this physician to prescribe Luvox to this patient for ADHD and autism.

Relators also argued in the hearing that the call notes support that a physician who prescribed Luvox for bipolar disorder in 2001 after receiving a pitch logged in a call note in 1999 supports their claim because this physician was an extremely frequent target for a number of years. However, the evidence shows only a pitch in 1999 in which the sales representative stated, "LU-uses for autistic kids. Works well. Needed samples." Dkt. 596, App. A2.3. This call note does *not* reflect that the sales representative pitched Luvox for off-label uses. It reports what the physician said. Even if the court disregards the hearsay problem, a reasonable jury could not determine, based on this evidence, that the physician prescribed Luvox for bipolar disorder in 2001 because he or she received an off-label message from an SPI sales representative in 1999.

Relators next point to a physician who prescribed Aceon for "dmii wo cmp nt st uncntr." Dkt. 596, App. A1.3. According the Relators, this means: "diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled." *Id.* The description of the pitches in the call notes is: "diabetic kidney aceon." Without testimony from the sales representative, the jury would need to conclude from this description that the sales representative

gave an off-label pitch for Aceon about how it was allegedly beneficial for the diabetic kidney. SPI's expert points out, however, that the patient, while having a diagnosis relating to diabetes at this appointment, also had an on-label diagnosis for hypertension or malignant hypertension. While an inference that the physician may have chosen Aceon over other hypertension drugs due to the pitch is reasonable, there is still the issue of the prescription not really being off-label because the patient had a diagnosis of hypertension.

Relators point out that this same physician prescribed Aceon two days later for another off-label diagnosis—atherosclerosis. *See* Dkt. 596, App. A1.3. The pitch obviously related to diabetic kidney, not atherosclerosis, but Relators argue that the sales representative *must* have talked about the PROGRESS trial, which relates to atherosclerosis, too. The problem with this argument is that it is just that, an argument based on conjecture and speculation. Relators have presented no evidence that would lead a reasonable jury to conclude that the sales representative, who is not testifying and only wrote "diabetic kidney aceon," convinced this physician to prescribe Aceon for atherosclerosis, resulting in a false Medicaid claim.

Taking these examples, it becomes clear that even if there were no problems with the admissibility of the underlying claims data, which of course there are, a reasonable jury could not get from this incredibly small number of claims isolated to one state to a scheme in which sales representatives across the country presented off-label information to physicians and caused them to prescribe the Drugs at Issue for nonreimbursible uses, resulting in off-label prescriptions being filled by Medicaid patients all over the country.

D. Summary Charts

The next issue relates to the summary charts that Relators attached as summary judgment

evidence. According to Relators' counsel, the summary charts summarize acts of off-label promotion and link them with the Texas and New York Claims Data. Dkt. 596, Ex. D4. Relators' counsel asserts that the "summarized information in these charts accurately and correctly presents the underlying material from the promotional evidence and claims data" and that the "actual descriptive call notes entered by the sales representative are relayed in full and verbatim." *Id.* Relators contend that to the extent the call notes and underlying data are admissible, they should be able to summarize the data for ease of reference under Federal Rule of Evidence 1006.

SPI objects to the summary charts because (1) they rely on the unauthenticated claims data; (2) they rely on call notes that contain hearsay; and (3) Relators cannot rely on attorney-created charts and offer no explanation to how they were created or whether they convey a complete picture. Dkt. 610. At the hearing, SPI also objected to the summary charts because if the summary charts were created by Relators' counsel, then counsel would need to testify regarding how she compiled them, and this would violate the advocate as a witness rule.

Under Federal Rule of Evidence 1006, a

> proponent may use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court. The proponent must make the originals or duplicates available for examination or copying, or both, by other parties at a reasonable time and place. And the court may order the proponent to produce them in court.

Fed. R. Evid. 1006. The Fifth Circuit has instructed that "summary charts are, in the trial court's discretion, ordinarily admissible when:

> (1) the charts are based on competent evidence before the jury; (2) the primary evidence used to construct the charts is available to the other side for comparison in order that the correctness of the summary may be tested; (3) the person who prepared the charts is available for

> cross-examination; and (4) the jury is properly instructed concerning their consideration of the charts."

United States v. Winn, 948 F.2d 145, 159 (5th Cir. 1991); *see also Shell Offshore, Inc. v. Tesla Offshore, L.L.C.*, No. 13-6278, 2016 WL 541445, at *3 (E.D. La. Feb. 11, 2016) (citing these factors and ruling that a summary chart was appropriate where underlying invoices totaled more than eleven thousand pages, noting that there was no dispute regarding the accuracy of the summary, and deferring ruling on the admissibility of the charts until trial when the proponent would attempt to lay a foundation for their admissibility). SPI contends that it would be inappropriate for Relators' counsel to serve as a witness and thus be subject to cross-examination regarding the preparation of the charts, as required by the third prong.

SPI cites *Anderson v. Otis Elevator Co.* in support of its argument that Relators' counsel cannot serve as a witness to prove up the summary charts at trial. In *Anderson v. Otis Elevator Co.*, No. 11-10200, 2012 WL 5493383 (E.D. Mich. Nov. 13, 2012), the defendant moved to strike the declaration of the plaintiff's attorney. The plaintiff's attorney had attached several spreadsheets to the declaration and offered them as a summary of voluminous evidence under Rule 1006. *Anderson*, 2012 WL 5493383, at *1. The defendant argued that the exhibit was not an accurate, non-prejudicial summary of evidence but rather improper attorney argument offered by an improper proponent of the exhibit. *Id.* The plaintiff's attorney provided a detailed description of how she compiled the spreadsheets in her declaration. *Id.* at *2. The court, after discussing various inaccuracies and other problems with the summary, took issue with the fact that the summary was prepared by plaintiff's counsel. *Id.* at *5. The court noted that plaintiff's counsel would be required to testify about how she prepared the chart and be subject to cross examination before the chart could be admitted into

evidence. *Id.* This would have placed counsel in the role of "advocate-witness," which was a violation of Michigan Rule of Professional Conduct 3.7. *Id.* That rule bars lawyers from acting "'as advocate at trial in which the lawyer is likely to be a necessary witness.'" *Id.* (quoting Mich. Rule of Professional Conduct 3.7). The court also was concerned that the summary was "not summarizing one piece of particularly voluminous evidence, but rather attempting to compile various pieces of evidence, some of which are not voluminous at all, into a summary that demonstrates Plaintiffs' particular view of the evidence." *Id.* The court, thus, did not allow the evidence. *Id.* at *11.

The Texas Disciplinary Rules of Professional Conduct similarly prohibit the lawyer to also be a witness necessary to establishing an essential fact. Under Rule 3.08:

> A lawyer shall not accept or continue employment as an advocate before a tribunal in a contemplated or pending adjudicatory proceeding if the lawyers knows or believes that the lawyer is or may be a witness necessary to establish an essential fact on behalf of the lawyer's client, unless:
> (1) the testimony related to an uncontested issue;
> (2) the testimony will relate solely to a matter of formality and there is no reason to believe that substantial evidence will be offered in opposition to the testimony;
> (3) the testimony relates to the nature and value of legal services rendered in the case;
> (4) the lawyer is a party to the action and is appearing pro se; or
> (5) the lawyer has promptly notified opposing counsel that the lawyer expects to testify in the matter and disqualification of the lawyer would work substantial hardship on the client.

Tex. Disciplinary Rules of Prof'l Conduct R. 3.08. The comments indicate that "the principal concern over allowing a lawyer to serve as both an advocate and witness for a client is the possible confusion that those dual roles create for a finder of fact. . . . If . . . the lawyer's testimony concerns a controversial or contested matter, combining the roles of the advocate and witness can unfairly prejudice the opposing party." *Id.* (comments).

Here, while Relators contended during the hearing that all of SPI's objections were "technical," and the court anticipates that Relators believe any testimony about how the summary was compiled would likewise be only technical and not necessarily a controversial or contested matter, it is clear from the arguments at the hearing that the person creating the charts will indeed be subject to stringent cross examination regarding, for instance, why certain information was included and other information left out. Thus, even if the underlying data were admissible, the summary charts are not admissible because they were apparently prepared by Relators' lead counsel, who cannot serve as the proponent of the charts at trial.

IV. CONCLUSION

The court agrees, to some extent, with Relators' contention that they are not required to provide the court or Relators with a precise universe of claims to survive summary judgment. *See Pogue*, 565 F. Supp. 2d at 161. They do not have to "produce evidence of every single claim submitted to the Government, *provided* [they] can highlight sufficient evidence of claims submission in general." *Id.* However, since the Relators cannot provide any claims data that would be admissible at trial, for the reasons highlighted above, they cannot highlight any evidence of claims submission. And even if they could, they have not highlighted enough claims that a reasonable jury could determine resulted from off-label promotion to support their claim of a nationwide scheme resulting in false Medicaid claims. Accordingly, SPI's motion for summary judgment on the off-label promotion claims is **GRANTED**. The parties agreed at the hearing that these were the only

remaining claims. Thus, all of the outstanding motions to exclude evidence, which are contained at docket entries 479, 483, 484, 492, 499, 500, and 507 are **DENIED AS MOOT**. A final judgment will be issued concurrently with this order.

Signed at Houston, Texas on March 31, 2016.

Gray H. Miller
United States District Judge